PTO/SB/33 (07-05) Dbc Code: AP.PRE.REQ Approved for use through xx/xx/200x. OMB 0651-00xx U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE der the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Docket Number (Optional) PRE-APPEAL BRIEF REQUEST FOR REVIEW BJA338D **Application Number** Filed I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first-slass mail 235 in an envelope addressed to "Mail Stop AF, Commissioner for 7/10/2003 10/617,917 Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] First Named Inventor W. Neuberger Signature Art Unit Examiner Typed or printed Bolesh J. Skutnik 3739 Shay, D. name Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the applicant/inventor. Signature assignee of record of the entire interest. Bolesh J. Skutnik, Ph.D, JD See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. Typed or printed name (Form PTO/SB/96) X attorney or agent of record. 36,347 413-525-8222 Registration number Telephone number attorney or agent acting under 37 CFR 1.34. 5/12/2006 Registration number if acting under 37 CFR 1.34 \_ NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

\*Total of

forms are submitted.



onlicant

Wolfgang Neuberger

Serial No.

10/617,917

Filed

07/10/2003

For

Fiber Assisted Irradiation System and Method for Biostimulation

Examiner

David M. Shay

Art Unit

3739

I hereby certify that this correspondence is being deposited with the United States Postal Service as express mail, EQ 081377801 US, in an envelope addressed to: Mail Stop: AF, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on:

Date

May 12, 2006

Bolesh J. Skutnik

Signature

## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF

Commissioner for Patents

PO Box: 1450

Alexandria, VA 22313-1450

Sir:

In response to the Advisory Action dated 4/3/2006, rejecting the Amendment dated March 14, 2006, we request that you please review this continued rejection:

On December 29, 2005, Examiner Shay issued a final rejection of Claims 1, 3, 4, 6, 8, and 9 under 35 U.S.C. 103(a); Claims 2, 5, and 7 under 35 U.S.C. 103(a); Claim 10 under 35 U.S.C. 103(a); Claim 11 under 35 U.S.C. 103(a) and Claim 13 under 35 U.S.C. 103(a). This final rejection merely repeated verbatim the same rejections in the office action of 6/28/2005.

In the first rejection, the Examiner states on page 2, second paragraph, "McDaniel teaches a device and method for irradiating tissue to produce biostimulation using optical fibers, wherein any type of tissue can be irradiated. Dzbby (sic) teaches the use of oligomode optical fibers. {This is the heart of the evidence produce by the Examiner and similarly in the other rejections} It would have been obvious to the artisan of ordinary skill to employ a device and method as taught by Dabby in the device and method of McDaniel, since McDaniel proves no particular structure for the fiber optic applicator (underlining added to show clear errors), or, alternatively, to employ the device and

method of McDaniel in the device and method of Dabby, since the device and method of Dabby is tided (sic) to no particular application {underlining added top show clear error}, thus producing a device and method such as claimed."

Reference is made to MPEP 706.02(j), see Exhibit 1, wherein it states, "the examiner should set forth in the Office action: (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate, ..."

Also noted to establish a *prima facie* case, "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

The Examiner has repeatedly failed to provide any such support for these rejections, which has forced the applicant to only surmise the factual support for the conclusitory statements made by the Examiner as the above demonstrates in responding to these statements.

As further noted in MPEP 2144.08, Section III, page 2100-160 to 161, see Exhibit 2, "the findings should clearly articulate {underling added} which portions of the reference support any rejection. Explicit findings on motivation or suggestion to select the claimed invention should also be articulated {underling added} in order to support a 35 U.S.C. 103 ground of rejection. .... Conclusory statements of similarity or motivation, without any articulated rationale or evidentiary support, do not constitute sufficient factual findings." {underlining added}

In response to this vague rejection (about 25 words in the factual section), the applicant has provided almost two and half pages of detailed explanation (about 700 words) which clearly indicates that neither reference teaches, motivates, the combination; there is no expectation of success reasonable or otherwise. Also, the references should teach all of the claim limitations.

In the final rejection of these claims, the Examiner notes as to the McDaniel and Dabby references, see Page 3, first half of the page, "The examiner has specifically specified the motivation in the final sentence of the rejection. In addition to these

motivations is also noted that the device of Dabby reduces spending losses. This would also be motivation to include the fiber of Dabby, the device of McDaniel as more of the therapeutic radiation would reach the treatment site, despite bends in the fiber."

The last sentence of this rejection states, "It would have been obvious to the artisan of ordinary skill to employ a device and method as taught by Dabby in the device and method of McDaniel, since McDaniel provides no particular structure for the fiber optic application, or, alternatively, to employ the device and method of McDaniel in the device and method of Dabby since the device and method of Dabby is tided(sic) to no particular application, thus producing a device and method such as claimed."

Firstly, this does not <u>clearly articulate</u> the motivation and there is no factual support for such assertions, whatever that may be. The Examiner contends that the Dabby device can be used in McDaniel and/or the McDaniel device can be used in Dabby. Such a nebulous and contorted statement of motivation provides the applicant little to attack and merely forces the applicant to go the extra mile in responding to this rejection. It merely states the same conclusion in two directions.

Firstly, there is no reason to combine these two references.

Secondly, the applicant contends that this does not constitute sufficient factual findings. The McDaniel reference certainly discloses unique "structure" that typically is a flat panel of illuminating sources such as LEDs feeding through optical fibers, for example, for the treatment of various skin conditions. See Figure 4 of McDaniel. The use of LEDs is almost totally supported by McDaniel with laser diodes mentioned in the examples, in particular. Further, the Examiner claims that Dabby is tied to no particular application which is not true. Dabby's fibers are directed at communication and data fibers, not fibers that carry multichromatic radiation from LEDs, for example, for only a few feet in the devices shown. See, for example, Dabby, at Col. 7, lines 36 to 38, "the optical waveguide formed in accordance with the invention is installed in a system with waveguide total length being in excess of 9000 meters." See Col. 5, lines 53 to 54, "telecommunication grade fibers" See also, Col. 1, lines 16 to 19, "telecommunications", "high capacity data processing", "other communications environment". The Examiner has merely ignored the teachings of these references, making statements not supported by the teachings of these references, and combined them solely by ignoring these teachings

to arrive at an unworkable combination in an attempt to find elements of the present invention.

Clearly, why would someone use an optical fiber design for use in lengths in excess of 9000 meters for telecommunications and data processing in a doctor's office setting where clearly the fiber lengths are only a few feet if that. Further, the Examiner claims that the use of Dabby's optical fibers would reduce the cost in the device of McDaniel as motivation. The examiner, apparently using the fact that telecom fibers are inexpensive compared to multimode specialty fibers, presumes that oligimode fibers, since Dabby mentions them in only a telecom context, must also be cheaper than multimode fibers. The oligimode fiber is more expensive than a simple multimode of similar size. His presumption is clearly incorrect because telecom fibers are cheaper than other fibers because they are made on dedicated towers at speeds 10-30 times faster than multimode fibers; they use less glass than most multimode fibers; and they are sold in enormous volumes compared to non-telecom fibers. Furthermore, the Dabby fiber operates as a "virtual single mode" device or even a dual mode but with the second order mode being suppressed. See Abstract. Therefore, the motivation provided by the Examiner is not found in the references but in a desire to combine these references to meet the elements in the present invention. MPEP 706(j), page 700-48, second column at top, states that the motivation for combining and success must be both found in the references, not in applicant's disclosure. {underlining added}

In the final rejection and in response to the applicant's statement, the Examiner on page 2 of the Final Rejection, notes, "Applicant then asserts that the McDaniel reference fails to disclose a 'source for leaking radiation along the length of the waveguide'. The examiner must respectfully point that the requirement in the claim is that the radiation leak at "at least one location along the length of the fiber" is satisfied by the exiting of the radiation at the fiber end, ..."

The Examiner further continued the prior rejection with a verbatim statement of these rejections.

In the Applicant's after final response, a detailed explanation was made as to the term "leak". See page 6, third paragraph. After this section the applicant goes into a detailed explanation as to why the two references of McDaniel and Dabby can not be combined. See Page 6, last paragraph to Page 8, first full paragraph.

The Applicant in response to this final rejection submitted an after final amendment on March 14, 2006, and, in particular, took issue with the Examiner's interpretation of the word "leak" meaning radiation coming from the end of the fiber. This is a technical word in the optical fiber art and has a specific meaning as provided by the applicant in three Exhibits to mean radiation that comes from the side of an optical fiber, certainly not the radiation from the end of the fiber as contended by the Examiner.

In an advisory action dated 4/3/2006, the Examiner claims he reconsidered the claims but did not allow any claims, and supported such by "The publications submitted do not show that the examiner's interpretation is exclused {should be excluded} from the proper definition of the term "leaky", for example, the fiber-optics glossary from which one of the submissions was gleaned does not have a definition for the term leak posted on its page for terms beginning with 'L'."

For the Examiner to demand that the applicant find a definition that excludes his interpretation of the term "leak" or "leaky" is totally unjustified. This manner allows the Examiner to create any interpretation of words and then force the applicant into a position of proving that his interpretation is not supported by the art meaning of the word. Why would a dictionary or the like make such an exclusionary statement as demanded by the Examiner. The meaning of the word "leak" from an optical fiber is well known in the art and certainly does not include the light leaving from an output end of the optical fiber and to have a dictionary state such is beyond a reasonable demand. Even Dabby describes the process of energy "leak," "energy losses result because energy is radiated out the side of the waveguide." Col. 1, lines 52 to 53.

It is therefore respectfully asserted that there are insufficient facts to support the Examiner's rejection under 35 U.S.C. 103(a) and further that statements made by the Examiner are clearly in error and purposively created to make the rejection without references to specific statements in the references for support.

Dated: May 12, 2006

CeramOptec Industries, Inc. 515 Shaker Road East Longmeadow, MA 01028

Phone: (413) 525-8222

Respectfully submitted,

Bolesh J. Skutnik, PhD, JD

Reg. No. 36,347

Attorney for Applicants

Fax: (413) 525-0611